CORPORATE NEWS

PAION ANNOUNCES SUBMISSION OF NEW DRUG APPLICATION FOR REMIMAZOLAM BY ITS LICENSEE HANA PHARM IN SOUTH KOREA

Aachen (Germany), 30 December 2019 – The Specialty Pharma Company PAION AG (FSE: PA8) today announces that its South Korean remimazolam licensee Hana Pharm has informed PAION about the submission of a New Drug Application (NDA) to the Ministry of Food and Drug Safety (MFDS) for remimazolam in the indication general anesthesia.

Dr. Jim Phillips, CEO of PAION AG, commented: "*We congratulate our partner Hana Pharm on filing remimazolam in South Korea for a marketing authorization; this represents our 5th global filing for remimazolam, and further demonstrates the evolution of PAION towards a commercial business.*"

Dr. Younha Lee, President of Hana Pharm, announced: "*We are thrilled to have completed our NDA filing for remimazolam and Hana Pharm has reached this important step in South Korea, today. Once it is approved, remimazolam will be rewriting and shifting the total paradigm of general anesthesia and later on, the one of the procedural sedation treatment in South Korea. We really appreciate PAION for the regulatory support and look forward to building a rewarding partnership between two companies continuously.*"

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About remimazolam

Remimazolam is an ultra-short-acting intravenous benzodiazepine sedative/anesthetic that has shown positive results in clinical Phase III trials. In the human body, remimazolam is rapidly metabolized to an inactive metabolite by tissue esterases and is not metabolized by cytochrome-dependent hepatic pathways. Like other benzodiazepines, remimazolam can be reversed with flumazenil to rapidly terminate sedation or anesthesia if necessary. During clinical studies, remimazolam demonstrated efficacy and safety with around 2,500 volunteers and patients. Data so far indicate that remimazolam has a rapid onset and offset of action combined with a favorable cardio-respiratory safety profile.

PAION has completed clinical development of remimazolam for procedural sedation in the U.S. The U.S. licensee Cosmo submitted a New Drug Application (NDA) in procedural sedation in the U.S. in April 2019 and is responsible for any further development activities in the U.S. In Japan, licensee Mundipharma filed for market approval in general anesthesia in December 2018. In China, licensee Yichang Humanwell filed for market approval in procedural sedation in November 2018. In South Korea, licensee Hana Pharm filed for market approval in general anesthesia in December 2019. In Europe, PAION submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in procedural sedation in November 2019 and a Phase III trial in general anesthesia is ongoing.

In addition to procedural sedation and general anesthesia, based on positive Phase II study results, ICU sedation beyond 24 hours is another possible attractive indication for further development in the EU by PAION as well as by its licensees in other territories.

Remimazolam is partnered in the U.S. (Cosmo Pharmaceuticals), Japan (Mundipharma), China (Yichang Humanwell), Canada (Pharmascience), Russia/CIS, Turkey and the MENA region (R-Pharm) as well as South Korea (Hana Pharm). For all other markets outside the EU, remimazolam is available for licensing.

About PAION

PAION AG is a publicly listed specialty pharmaceutical company developing and aiming to commercialize innovative drugs for out-patient and hospital-based sedation, anesthesia and critical care services. PAION's lead compound is remimazolam, an intravenous, ultra-short-acting and controllable benzodiazepine sedative/anesthetic drug candidate. PAION has completed clinical development for use in procedural sedation in the U.S. and its licensee Cosmo Pharmaceuticals submitted a New Drug Application in April 2019, for which a PDUFA decision date of 05 April 2020 has been set. In Japan, licensee Mundipharma filed for market approval for remimazolam in general anesthesia in December 2018. In China, licensee Yichang Humanwell filed for market approval for remimazolam in procedural sedation in November 2018 and in South Korea, licensee Hana Pharm filed for market approval in general anesthesia in December 2019.

In Europe, PAION is seeking approval of remimazolam for general anesthesia and for procedural sedation. PAION submitted a Marketing Authorization Application (MAA) for procedural sedation in November 2019. A Phase III trial in general anesthesia is ongoing.

Development for intensive care unit (ICU) sedation is part of the longer-term life-cycle plan for remimazolam.

PAION's mission is to be a leading specialty pharmaceutical company in the fields of anesthesia & critical care by bringing novel products to market to benefit patients, doctors & stakeholders in healthcare. PAION is headquartered in Aachen (Germany) with an additional site in Cambridge (United Kingdom).

PAION Contact

Ralf Penner
Vice President Investor Relations/Public Relations
PAION AG
Martinstrasse 10-12
52062 Aachen – Germany
Phone: +49 241 4453-152
E-mail: r.penner@paion.com
www.paion.com

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